Please join us for an upcoming discussion about EMPAVELI™

EMPAVELI™
(pegcetacoplan) injection
1080 mg/20 mL solution

FEATURED SPEAKER
Jorge P. Leguizamo, MD, FACP
Director of the Hematology Group
Georgia Cancer Specialists
Lawrenceville, GA

WHEN
Thursday, February 24, 2022
6:30 PM PT

WHERE
Fleming's Prime Steakhouse & Wine Bar
180 El Camino Real
Palo Alto, CA 94304

To register for this program, visit www.ApellisRSVP.com/3974-9 or call 833-528-3617. You may also contact your Apellis Representative, Jonelle Wilhelmsen to register or with any questions at 206-229-1133 or via email at Jonelle.Wilhelmsen@apellis.com.

To facilitate a meaningful educational discussion, this program is only intended for healthcare professionals in the designated medical specialties. No guests can be accommodated. This is a promotional program, and no CME credits are offered.

INDICATION

EMPAVELI™ (pegcetacoplan) is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life-threatening or fatal if not recognized and treated early. Use of EMPAVELI may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.**
- **Vaccinate patients at least 2 weeks prior to administering the first dose of EMPAVELI unless the risks of delaying therapy with EMPAVELI outweigh the risk of developing a serious infection.**
- **Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate immediately if infection is suspected.**

EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the EMPAVELI REMS, prescribers must enroll in the program.

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- Not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism
- Unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae*

Please see additional Important Safety Information on next page and accompanying full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib). To reduce the risk of infection, all patients must be vaccinated against these bacteria according to the most current ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI.

For patients without known history of vaccination, administer required vaccines at least 2 weeks prior to receiving the first dose of EMPAVELI. If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.

Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI REMS

Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers must enroll in the program and must counsel patients about the risk of serious infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated against encapsulated bacteria. Enrollment and additional information are available by telephone: 1-888-343-7073 or at www.empavelirems.com.

Infusion-Related Reactions

Systemic hypersensitivity reactions (e.g., facial swelling, rash, urticaria) have occurred in patients treated with EMPAVELI. One patient (less than 1% in clinical studies) experienced a serious allergic reaction which resolved after treatment with antihistamines. If a severe hypersensitivity reaction (including anaphylaxis) occurs, discontinue EMPAVELI infusion immediately, institute appropriate treatment, per standard of care, and monitor until signs and symptoms are resolved.

Monitoring PNH Manifestations after Discontinuation of EMPAVELI

After discontinuing treatment with EMPAVELI, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH levels along with sudden decrease in PNH clone size or hemoglobin, or reappearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues EMPAVELI for at least 8 weeks to detect hemolysis and other reactions. If hemolysis, including elevated LDH, occurs after discontinuation of EMPAVELI, consider restarting treatment with EMPAVELI.

Interference with Laboratory Tests

There may be interference between silica reagents in coagulation panels and EMPAVELI that results in artificially prolonged activated partial thromboplastin time (aPTT); therefore, avoid the use of silica reagents in coagulation panels.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥10% of patients) with EMPAVELI vs. eculizumab were injection-site reactions (39% v. 5%), infections (29% v. 26%), diarrhea (22% v. 3%), abdominal pain (20% v. 10%), respiratory tract infection (15% v. 13%), viral infection (12% v. 8%), and fatigue (12% v. 23%).

USE IN SPECIFIC POPULATIONS

Females of Reproductive Potential

EMPAVELI may cause embryo-fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential prior to treatment with EMPAVELI. Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.

Please see accompanying full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

Thank you in advance, and we look forward to your participation.

Jonelle Wilhelmsen, 206-229-1133, Jonelle.Wilhelmsen@apellis.com

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